

REMARKS

The changes to the rewritten claim above are shown in the attached Appendix. In the Appendix, additions are designated by underlining, and deletions are indicated with brackets.

In the Office Action, the Examiner rejected claims 1-5, 11-15, 19-22, 25 and 26 pursuant to 35 U.S.C. §103(a) as being unpatentable over Fujio et al. (U.S. Patent No. 5,471,988) in view of Ben-Haim (U.S. Patent No. 6,083,170). Claim 6 was rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Fujio et al. in view of Ben-Haim and in further view of Bernstein et al. (U.S. Patent No. 5,163,421). Claims 7, 8, 16 and 23 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Fujio et al. in view of Ben-Haim and in further view of Lemelson (U.S. Patent No. 5,845,646). Claims 9, 10, 17, 18 and 24 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Fujio et al. in view of Ben-Haim and in further view of Flesch (U.S. Patent No. 5,681,263). Applicants respectfully request reconsideration of claims 1-26, including independent claims 1, 11 and 19.

Independent claim 1 requires a memory-less adaptable section operable to maintain the position of the handle section relative to the transducer section without steering wires. Neither of Fujio et al. and Ben-Haim disclose these limitations.

Fujio et al. fix wires 29 to the distal end so that the wires 29 extend through the curvature part to the rotary element 37/31 (col. 11, lines 21-28). The curvature operation knob at the operation part 30 (i.e. handle) moves or curves the curvature part with the wires (col. 9, lines 50-53 and col. 11, lines 29-35). Fujio et al. provide steering wires for curving the probe while in use within a patient. Fujio et al. do not suggest an adaptable or adjustable section to maintain a position without steering wires.

Ben-Haim discloses a catheter with a sensor and alignment mechanism to deflect the catheter in response to the sensor (abstract). During use within a vessel, the sensor detects obstructions, and the alignment mechanism adjusts the catheter to proceed down the vessel while avoiding the obstructions (see FIGS. 1A, 1B, 3 and 5; col. 1, line 66-col. 2, line 5). To allow for adjustment while in the vessel, the alignment mechanism includes either steering wires (col. 12, lines 40-52) or a mechanism using a material with memory (col. 11, line 38-col.

12, line 29). At least three different embodiments of the alignment mechanism using a material with a memory are provided. For example, shape memory material (e.g., NiTi) is straight at one temperature but bend a particular way at another temperature (col. 11, lines 40-48). As another example, bi-metal elements bends a particular way or straightens in response to changes in temperature (col. 12, lines 10-29). As yet another example, piezoelectric crystals alternating with bendable joints of resilient material (e.g. spring steel) bend or straighten in response to voltage (col. 13, lines 6-28). A balloon based bending mechanism may also be used (col. 13, lines 34-38). The memory materials bias the catheter into a straight position, but then flex for angular adjustment to avoid obstructions (col. 11, lines 54-59; col. 12, lines 36-39; and col. 13, lines 11-24). For guiding or changes within the patient, Ben-Haim uses either steering wires or materials with a memory, such as spring steel. Ben-Haim does not suggest a memory-less adaptable section operable to maintain the position of the handle section relative to the transducer section without steering wires.

The act of bending the probe of Ben-Haim may be independent of previous acts of bending the probe. As noted by the Examiner, "the bending of the adaptable section of the probe is independent of past position." However, the steering wire free bending elements of Ben-Haim are not memory-less. The elements operate on the basic principle that the material has a memory or conforms to a particular position depending on application or lack of application of force. The elements are biased (e.g. spring steel, bi-metal or shape memory materials) to a particular position and are not memory-less.

Independent claim 11 requires an adjustable section having a device to maintain an adjusted bent position without a device for adjusting the adjustable section during use within the patient. As discussed above, both Fujio et al. and Ben-Haim include steering wires or other mechanism to allow adjustment of the bend within the patient, such as adjusting during surgery to obtain a different position of the transducer without requiring removal of the transducer from the patient. Such devices may be more versatile, but may also be more complex than a device to maintain an adjusted bent position without devices for adjusting the adjustable section during use within the patient. Fujio et al. and Ben-Haim do not suggest a

device to maintain a bent position without a device for adjustment during use within the patient.

Claim 19 requires rotating a first axis of a transducer housing relative to second axis of a handle housing prior to inserting the probe into a cavity of a patient and maintaining a relative position while the transducer housing is within the cavity. As discussed above, Fujio et al. and Ben-Haim disclose steering wires or other alignment mechanisms for changing the position of the transducer while inserted into the patient. Fujio et al. position a therapy device relative to a lesion by curving or bending the device while in the cavity (col. 12, line 59-col. 13, line 30). Figure 4 even shows the transducer inserted into the body cavity with the operators thumb on the curvature operation knob 31 for adjusting the curvature within the cavity. Ben-Haim use an alignment mechanism to navigate along a desired path through physiological tissue (col. 2, lines 1-5). Fujio et al. and Ben-Haim use steering to change the transducer position while within the patient, so do not suggest rotating a first axis of a transducer housing relative to second axis of a handle housing prior to inserting the probe into a cavity of a patient and maintaining a relative position while the transducer housing is within the cavity.

Dependent claims 2-5, 12-15, 20-22, 25 and 26 depend from the independent claims 1, 11 and 19 discussed above. Accordingly, these dependent claims are allowable for the reasons discussed above for the independent claims. Further limitations of the dependent claims distinguish these claims from the cited references. For example, Fujio et al. and Ben-Haim do not disclose: the adaptable section comprising a memoryless bendable section as claimed in claims 4 and 14. As discussed above, the non-steering wire embodiments use memory materials (e.g. shape memory metal, bi-metal or spring steel), so Ben-Haim does not suggest a memoryless bendable section. As another example, Ben-Haim does not disclose increasing the malleability in response to an external force as claimed in claims 25 and 26. Ben-Haim apply heat, voltage or other force to bend the probe, but do not suggest that the force also makes the probe more malleable.

Dependent claim 6 depends from the independent claim 1 discussed above, so is allowable for the reasons discussed above for independent claim 1. Claim 6 is also allowable because a person of ordinary skill in the art would not have been motivated to use the aluminum tip of Bernstein with the probes of Ben-Haim or Fujio et al. Bernstein use therapeutic ultrasound transmitted from the tip of the device for angioplasty (col. 2, lines 6-15 and col. 2, lines 24-40). Aluminum alloys are used on the extreme tip due to good acoustic energy transmission qualities for application of the therapeutic ultrasound (col. 2, lines 29-55 and col. 6, lines 1-56). Ben-Haim and Fujio et al. rely on steering wires or memory material for controlling the curvature between a handle and transducer to position the transducer. A person of ordinary skill in the art would not have used the aluminum tip of Bernstein as part of the much different steerable section between the handle and the transducer. The acoustic transmission properties of the steering portion between the handle and transducer do not matter for the probes of Ben-Haim and Fujio et al..

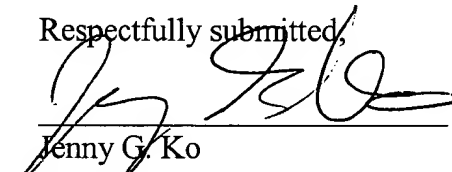
Dependent claims 7, 8, 16 and 23 depend from the independent claims 1, 11 and 19 discussed above, so are allowable for the reasons discussed above for the independent claims. These dependent claims are also allowable for another reason. A person of ordinary skill in the art would not have used the ball and socket joints of Lemelson with the teachings of Ben-Haim and Fujio et al. Lemelson teaches away from using the ball and socket joints. Steering wires are connected with each ball and socket joint within the catheter (col. 13, lines 19-27). Lemelson notes that “steering systems of the foregoing types [including the ball and socket joints] require internal pull wires or other internal structures which occupy space within the lumen of the catheter. Desirably, however, the catheter diameter should be as small as possible to minimize insertion trauma and unwanted damage to surrounding tissue” (col. 13, lines 54-59). Lemelson provides an alternative using magnets (col. 13, lines 60-64). Lemelson teaches away from using the ball and socket joints due to the size requirements, so a person of ordinary skill in the art would not have used the ball and socket joints of Lemelson with the probe teachings of Ben-Haim and Fujio et al.

Dependent claims 9, 10, 17, 18 and 24 depend from the independent claims 1, 11 and 19 discussed above, so are allowable for the reasons discussed above for the independent claims. Claims 9, 10 and 17 require the latch to be part of the adaptable section between the handle and the transducer. The ball latches 34 and indentations 36 of Flesch are part of the handle, not between the handle and transducer. A person of ordinary skill in the art would not have used a rotatable control using the ball latches 34 in the handle as part of the separate bending or steered section of Ben-Haim or Fujio et al.

CONCLUSION:

Applicants respectfully submit that all of the pending claims are in condition for allowance and seeks early allowance thereof. If for any reason, the Examiner is unable to allow the application but believes that an interview would be helpful to resolve any issues, he is respectfully requested to call the undersigned at (650) 694-5810 or Craig Summerfield at (312) 321-4726.

Respectfully submitted,


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APPENDIX

1. (twice amended) In an intraoperative ultrasound probe for insertion into a patient, the intraoperative ultrasound probe having a handle section and a transducer section, the transducer section including a transducer, an improvement comprising:

an adaptable section between the handle section and the transducer section, the adaptable section operable to allow bending movement of and maintain the position of the handle section relative to the transducer section without steering wires, the adaptable section being memory-less.

11. (twice amended) An intraoperative or endocavity ultrasound probe for insertion into a cavity or surgical incision of a patient, the probe comprising:

a transducer housing;

a handle housing; and

an adjustable section joining the transducer housing to the handle housing, the adjustable section having a flexible covering and a device to maintain an adjusted bent position of the transducer housing to the handle housing without [steering wires] a device for adjusting the adjustable section during use within the patient.

19. (amended) A method for using an intraoperative or endocavity ultrasound probe, the method comprising the acts of:

(a) inserting the probe into a cavity of a patient;

(b) rotating a first axis of a transducer housing relative to second axis of a handle housing prior to (a); and

(c) maintaining a relative position of the first and second axes [during (a)] while the transducer housing is within the cavity.